

Reif '086 was cited by applicant in the initial IDS filed on January 23, 2002. The subject matter of Reif '200 is therefore not new to the prosecution of this patent application. It has been of record for nearly three years.

The Reif '086 patent was considered by the predecessor Examiner, Dr. Liliana DiNola-Baron, as evidenced by her initials on a copy (enclosed) of applicant's initial IDS and her certification that the art was considered on March 1, 2004.

Dr. DiNola-Baron issued the first Action on the merits in this case. It did not cite the Reif '086 patent against any claim.

Dr. DiNola-Baron also considered the Reif '086 reference with connection with the corresponding PCT application, Serial No. US00/21149 filed August 3, 2000, published as WO 01/10464 on February 15, 2001. Initially in the International Search Report of 15 September 2000, Dr. DiNola-Baron found Reif '086 to be in category Y with respect to claims 1-62. However, in her Final Report, claims 1-62 were found to be patentable over Reif '086 and the other art of record. A copy of the Final Report is also enclosed. No amendments were made in claims 1-28 in the U.S. or PCT cases other than correction of minor typographical errors

There is no reason that the submission of the parent Reif patent should somehow cause the earlier determinations as to its lack of relevance to the pending claims to change. No new subject matter is present in the Reif '200 patent. The pending claims are as patentable over the Reif '200 patent as they were over the Reif '086 patent. Reif teaches depositing doses of an active ingredient on a web, sealing it between the web and a cover layer, and cutting the sealed web into single dosage units. This is not the present invention, nor does it suggest the present invention.

Both Reif patents have no teaching or suggestion of a pharmaceutical dosage form that has "a layer of material bearing a microrelief that conveys information" as required by the pending claims 1-6 or core with a solid outer layer and a microrelief in said layer as required by claims 7-28. (Claim 18 specifies that the layer can also assume the role of the core in containing the pharmaceutically active substance.) Nor does either Reif patent have a teaching or suggestion that the material is "thermoformable" to receive this microrelief, or "stable" to maintain the microrelief suitable for a pharmaceutical dosage form. Nor does either Reif patent teach or suggest any of the novel features of the dependent claim in combination with the features of independent claims 1 and 7. For example, there is no teaching or suggestion in Reif '200 or '086 that the constituent material of the layer carrying a microrelief can display information that indicates the history and efficacy of the dosage form. See, e.g., claim 19 and the claims depending from

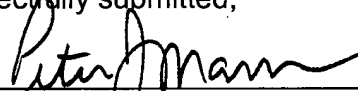
Applicant also herewith respectfully requests that the Examiner reconsider whether the Final rejection in this case is proper. Under Sec. 706.07(a) of the MPEP, a final rejection on a second Action is proper "except when the examiner introduces a new ground of rejection [here, the Section 102(b) rejection of the pending claims based on Reif '200] that is ... [not] based on information submitted in an information disclosure statement...." Here, the same subject matter was already before the examiner; the filing of the information disclosure statement in June of 2004 did not present new or non-cumulative subject matter.

In view of the foregoing comments, applicant urges that the pending claims 1-28 patentably distinguish over the art of record and are otherwise in condition for allowance.

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Respectfully submitted,

By



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